

AMENDED IN ASSEMBLY JULY 3, 2014

AMENDED IN ASSEMBLY JUNE 4, 2014

AMENDED IN SENATE MARCH 26, 2014

SENATE BILL

No. 835

Introduced by Senator Hill

January 6, 2014

An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as amended, Hill. Food animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that livestock or poultry raised for the production of human food are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, that is administered to food animals, as defined, through feed or drinking water, unless prescribed requirements are met. The bill would, except as specified, provide that a medically important antimicrobial drug currently registered with the ~~department~~ *Department of Food and Agriculture* that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would ~~require~~

prohibit a person from administering a medically important antimicrobial through feed or drinking water except pursuant to a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug administered to food animals through feed or drinking water described. Because a violation of the bill's provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 14288 of the Food and Agricultural Code
- 2 is amended to read:
- 3 14288. The secretary shall refuse to register a livestock drug
- 4 if he or she finds any of the following is true of the drug:
- 5 (a) It is of little or no value for the purpose for which it is
- 6 intended to be used.
- 7 (b) It is dangerous to the health of livestock if used in accordance
- 8 with the instructions.
- 9 (c) The instructions for use do not contain adequate warnings
- 10 against use in those conditions, whether pathological or normal,
- 11 under which its use may be dangerous to the health of livestock
- 12 or humans who consume products from the livestock, or against
- 13 unsafe dosage, unsafe duration of use, or unsafe methods of
- 14 administration.
- 15 (d) If the application and the accompanying material, data, and
- 16 information do not comply with the requirements of this chapter
- 17 or are insufficient to permit the secretary to make the
- 18 determinations that are required by this section.
- 19 (e) It is a medically important antimicrobial drug, as defined in
- 20 Section 18770, that is administered to food animals, as defined in
- 21 Section 4825.1 of the Business and Professions Code, through feed
- 22 or drinking water, unless the drug complies with Section 18771.

1 SEC. 2. Article 4.5 (commencing with Section 18770) is added
2 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural
3 Code, to read:

4
5 Article 4.5. Medically Important Antimicrobial Drugs
6

7 18770. For purposes of this article, the following definitions
8 apply:

9 (a) "FDA" means the federal Food and Drug Administration.

10 (b) "Food animal" has the same meaning as defined in
11 subdivision (c) of Section 4825.1 of the Business and Professions
12 Code.

13 (c) "Medically important antimicrobial drug" means an
14 antimicrobial drug listed in Appendix A of the FDA Guidance for
15 Industry #152, including a critically important, highly important,
16 and important antimicrobial drug, as that appendix may be
17 amended, unless the secretary determines that the amendment to
18 the appendix includes a drug that is not a critically important,
19 highly important, or important antimicrobial drug.

20 (d) "Veterinary feed directive" is the directive described in
21 Section 354 of Title 21 of the United States Code.

22 18771. To comply with FDA Guidance for Industry #213,
23 dated December 2013, a medically important antimicrobial drug,
24 including a combination drug incorporating a medically important
25 antimicrobial drug, shall meet all of the requirements in the
26 guidance document, including, but not limited to, the following:

27 (a) To reflect the need for professional oversight by a licensed
28 veterinarian, the manufacturer shall remove from the approved
29 production uses on the label of the medically important
30 antimicrobial drug or combination drug the production indications,
31 including, but not limited to, "increased rate of weight gain" or
32 "improved feed efficiency."

33 (b) The manufacturer shall revise the condition of the use of the
34 medically important antimicrobial drug or combination drug from
35 over the counter availability to a marketing status requiring
36 veterinary prescription, including, but not limited to, the following:

37 (1) For medicated feed products, a change from over the counter
38 to veterinary feed directive.

39 (2) For medicated drinking water products, a change from over
40 the counter to veterinary prescription.

(c) When administered through feed or drinking water, the medically important antimicrobial drug may only be used to treat, prevent, or control disease under the supervision of, or by prescription from, a licensed veterinarian.

~~18772. There shall be a~~ *A person shall not administer a medically important antimicrobial drug through feed or drinking water except pursuant to a veterinarian-client-patient relationship to ensure that a medically important antimicrobial the drug administered to food animals through feed or drinking water is* used in a manner that is consistent with professionally accepted best practices. For the purposes of this section, a “veterinarian-client-patient relationship” is a relationship meeting the requirements of Section 2032.1 of Title 16 of the California Code of Regulations.

18773. (a) (1) If a medically important antimicrobial drug, or combination drug, for use in food animals is registered with the department as of January 1, 2015, and the drug does not comply with Section 18771, the manufacturer of the medically important antimicrobial drug, or combination drug, shall have until January 1, 2017, to reregister the drug with the secretary. The secretary shall refuse to reregister the drug unless it complies with Section 18771.

(2) Notwithstanding paragraph (1), if a drug label reviewed by the FDA under the Guidance for Industry #213 is delayed beyond January 1, 2017, the secretary shall have the authority to continue registering the drug during the FDA’s review period.

(3) If revisions to the veterinary feed directive cause the FDA to delay implementation of the Guidance for Industry #213, the secretary shall have the authority to extend the time period by which a manufacturer is required to reregister the drug pursuant to paragraph (1) to be consistent with the delay in the implementation of the guidance. If the secretary extends the time period for reregistration, the extension shall not be later than the federal implementation date of the guidance.

(b) If revisions to the veterinary feed directive cause the FDA to revise the Guidance for Industry #213, the secretary shall have the authority to promulgate regulations to ensure that California law is consistent with the revisions to the guidance.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the penalty
4 for a crime or infraction, within the meaning of Section 17556 of
5 the Government Code, or changes the definition of a crime within
6 the meaning of Section 6 of Article XIII B of the California
7 Constitution.

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